

The Broad Ethical Perspectives of Data Sharing

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Data Sharing

- Research-based
- Clinical effectiveness and quality improvement
 - Prevention
 - Diagnosis
 - Treatment
 - Research to advance practice
 - Teaching and training

Data Sharing

- **Risk-benefit balance**

- Risk of loss of privacy and confidentiality
- Risk of infringing on the autonomy of subjects
- Risk of unethical doubt manufacturing and conflict of interest
- Benefit of health advancement and prevention
- Benefit of Cost-effectiveness
- Better research and study design in pooling data
- Sustaining disciplines such as environmental epidemiology

Data Sharing

Research Data type

- Questionnaire/written data
 - Re-analyses
 - New hypothesis
- Biomonitoring/Biobank data
 - Exposure assessment (new, re-analyze old)
 - Genetic/Omics assessment (new, re-analyze old)
- Linking datasets to create a new data set
 - Gene X Environment,
 - Medical records X Environmental exposures

Personal Identifiers

Name	Vehicle ID	ZipCode/address
Phone	License number	Medical Record
Fax	IP Address #	Health Plan number
email	Account #	age
SS	URL	
Biometrics	Device identifiers	
Face image	Other Unique identifiers	

Personal Identifiers

- All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes,
- except for the initial three digits of a zip code, if :
 - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

The Players

- The researcher
 - The original investigator
 - The secondary investigator
- The subject and community
- The organization
 - Funding organization
 - The owner/storing organization

Researcher

- Original PI
 - Hypothesis
 - Appropriate design to answer the hypothesis
 - Consent
 - Ownership
 - Additional benefit from data sharing if involved
 - Burden and cost of data mining or maintenance
 - Transparency and not obstructive

Researcher

- Secondary PI
 - Hypothesis driven or post-hoc analyses
 - Can the original design appropriately address the question?
 - Conflict of interest (litigation, commercial)
 - Consent of original subjects for this analyses
 - Sharing of costs
 - Level playing field: reciprocal data sharing for private entities

Subject

- Volunteered their data and do not own it
- Autonomy to decide which study uses their data
- May not have consented if they were asked for an open consent
- Promised results and feedback
- May not be reached to be re-consented
- Concerned about privacy and confidentiality when changing hands

The Community

- Requires involvement if Identifiable
- Indigenous populations (Havasupai Indians)
- Stigma
- Suffer Environmental Injustice
- Involvement in the original study approval process
- Can delay any data sharing
- Expects feedback and results

Data Sharing Organizations

- HMO, e.g. Kaiser, Medicare (*HIPAA, Data Linkage*)
- State and County Departments of Health (*IRB, State Regulations, inefficiency*)
- Registries (*HIPAA, Bureaucracy, inefficiency*)
- Federal Government (EPA, CDC, NCHS) (*Bureaucracy and politics, WB*)
- Universities (*Industry influence, IP, Revenue generating*)
- Industry (*Conflicts of interest*)
- NIEHS (*Funding*)

Data Sharing Access

- Data users
 - Environmental sciences need it the most
 - Climate change
 - Water contamination
 - Desert storms
- Data protectionists
 - Growing identity theft
 - Business of selling personal information
- Data obstructionists
 - Cell phone companies
 - Faulty regulations

Faulty Regulations

Pesticide levels among farmworkers

- UCSD IRB
- County Department of health
- Local community organization
- Farmworkers coalition
- Binational border health environmental task force
- California Department of Pesticide Regulation

Opposite Sides of the Table

- Data Owner
 - Requiring Zip codes for a publically available data set
- Data Seeker
 - Re-contacting pre-consented participants

International Setting

- Reconciling differences in regulations
- Lack of local IRBs and untrained researchers
- Transfer of data across borders
- The human genome
 - Quality; accessibility; responsibility of funders, generators, and users; security; transparency, accountability; integrity
- Data Sharing maximize global public benefit

Re-Analyses Guidelines

- Protecting the Public's interest
 - Cooperation of original authors, declaring conflicts of interest, independent advisory board created, agree on the hypothesis, proposal, results published regardless
- Protecting the Rights of Subjects
 - Respect privacy and consent for re-analyses
- Protecting the Right of the original and re-analyzing authors
 - Data ownership, open communication with original author, opportunity to comment before publication, allow original authors to publish first, providing funding
- Funding agencies establish guidelines on storage and access of data for secondary analyses

Public Health Surveillance Data

- Cancer Registries, Birth and Death Records
- Abuse of HIPAA and other Federal regulations
- More restrictive than anytime before
- De-identified linkage of data denied
- VA health data not reported to registries
- Negative impact on public health research and Practice
- Credit Agencies vs Health scientists
- Scientific community and professional organizations need to act

Data Sharing Ethical Challenges

- Inconsistency across IRBs and states
- Requiring multiple IRB approvals
- Verification of conflicts of interest
- Overcoming ownership obstacles
- Publication credit of Original vs Secondary PI
- General reluctance of participants for open consent
- Prioritizing the use of finite biobank samples

Concluding Remarks

- The NIEHS leverage as a funding agency
- Oversight of data sharing
- Provide funding for the process
- Sub committee to review ethical aspects
 - facilitates local IRB approval
 - Address conflicts of interest
 - Synchronize with the original data design and consent process
 - Data exchange and linkage

Concluding Remarks

- Risk Stratification checklist
- Pro-data users
- Research ethics training
- Unethical conduct of research happens
- The researcher bears the ultimate moral responsibility towards the study subjects and the integrity of his/her work